III. REMARKS/ARGUMENTS

Claims 6-10, 13-16, and 20-23 are pending. Claims 11-12 and 17-19 have been canceled without prejudice. Applicants respectfully request reconsideration of the present application.

A. Rejection Under 35 U.S.C. § 112

In the Office Action, claims 13 and 18 were rejected under 35 U.S.C. § 112, second paragraph on the grounds of indefiniteness. The Examiner stated that "the phrase 'protein-derived materials' in claim 13 (line 3) is vague and indefinite, as the meets and bounds of this claim is unascertainable... The term "lower" in claim 18 (line 2) is a relative term which renders the claim indefinite...."

With respect to the term "protein-derived" in claim 13, Applicants respectfully submit that the term "protein-derived" is recognized in the art to mean any polymer derived from any of the 20 amino acids. One skilled in the art would know that a protein derived material can be obtained from e.g., a plant or grain source such as soybeans, wheat or corn, as described in U.S. patent No. 5,128,159 at column 1, line 66 to column 2, line 1. Alternatively, a protein derived material can be obtained from an animal source, e.g., collagen, as described in U.S. Patent No. 5,522,888 at column 1, lines 55-57. Accordingly, the Examiner is respectfully requested to remove the indefiniteness rejection of claim 13 as "protein-derived" is an art recognized term.

With regard to the term "lower" in claim 18, it is noted that this claim has been canceled.

B. Rejection Under 35 U.S.C. § 102(e)

In the Office Action, claims 6-7, 9, and 11-19 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,133,974 (Paradissis et al.). The Examiner stated, *inter alia*, that "the instant invention and Paradissis both teach extended release drug formulations comprising a drug coated with matrix spheroids that are coated with an acrylic copolymer or ethylcellulose and comprise hydroxylower alkylcellulose or acrylic polymer, which is further

coated with a controlled release matrix comprising alkylcellulose or cellulose ether and a hydrocarbon and polyalkylene glycol." The Examiner further states in response to previous arguments that "the prior art teaches the identical chemical structure" and that the "prior art teaches extended release formulations ... which would inherently meet Applicant's functional language."

This rejection is respectfully traversed as the formulations of the present method claims are different than the formulations of the Paradissis reference as will be discussed below.

The present claims recite that the opioid analgesic is "contained in a controlled release matrix." This term is known to one skilled in the art to mean that the opioid analgesic is interdispersed in a material which provides for the controlled release of the drug. Typically, such matrix formulations are achieved by "mixing of the matrix material followed by compression of the material into tablets" as described in Pharmacy Review, page 53 (attached as Exhibit C). An example of a structure of a drug "contained in a controlled release matrix" is set forth below:

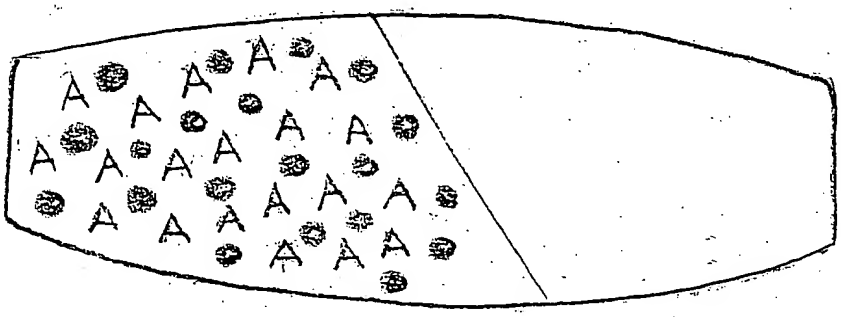

Fig. 1

In sharp contrast, the Parradissis reference describes extended release formulations comprising immediate release particles containing a core of drug, inert spherical substrate particles and binder, coated with talc; and an extended release particle comprising the immediate release particle coated with a dissolution modifying system (See: col. 3, lines 21-28). These coated bead formulations of the Paradissis reference are recognized to one skilled in the art as different than a matrix formulation, as evidenced by the separate discussions of these formulations on page 53 of Pharmacy Review. An example of "an extended release particle comprising the immediate release particle coated with a dissolution modifying system " is set forth below:

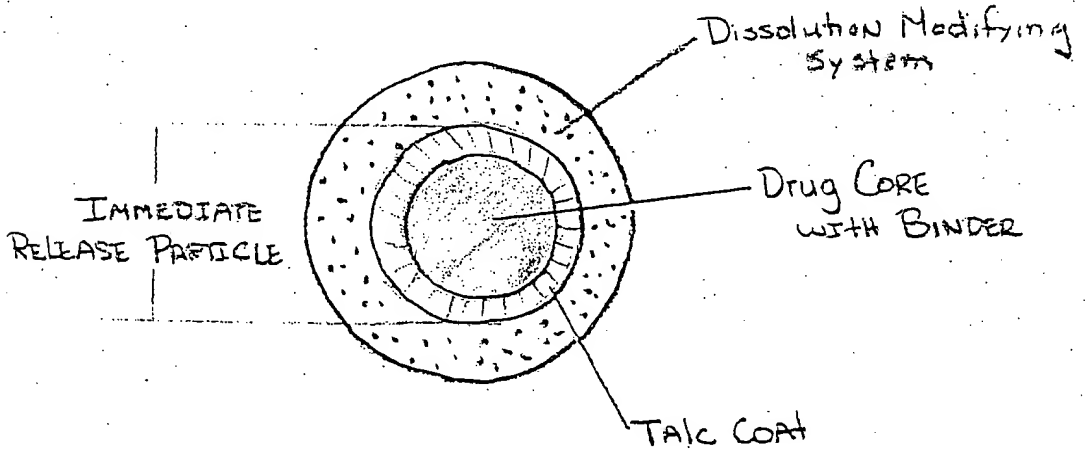

Fig. 2

In view of the arguments presented above, it is respectfully submitted that the formulations of the Paradissis reference are different than the formulations recited in the present method claims. Therefore, it is improper for the Examiner to rely on the doctrine of inherency in rejecting the present claims and removal of the anticipation rejection is requested.

Further, it is respectfully submitted that there is no indication that coated bead opioid analgesic formulations were ever made by Paradissis et al. Therefore, the doctrine of inherency based on Paradissis cannot be relied upon for any claim based on the present specification (e.g., a claim directed to opioid bead formulations with specific pharmacokinetic parameters) as one cannot establish the inherent characteristics of a composition that was never made.

Also, the coated bead formulations of Paradissis are not identical or substantially identical to the coated bead formulations disclosed, but not claimed in the present specification, for example, the Paradissis formulations require a talc coat, which is not contained in the examples of the present application. Therefore, it cannot be established that "the alleged inherent characteristic necessarily flows from the teachings of the prior art" which is necessary for a rejection based on inherency. (See Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

C. Rejection Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 8, 10 and 20-23 under 35 U.S.C. § 103(a) as being unpatentable over Paradissis et al. as applied to claims 6-7, 9, and 11-19 above. The Examiner stated that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute hydromorphone or oxycodone for morphine in Paradissis et al. because of the expectation of achieving equivalent pain relief....[or] to exemplify the formulations of Paradissis et al. as comparing at least 50mg of drug because of the expectation of achieving dosage amounts that are effective to treat different levels and forms of pain, and different weight amounts of patients."

In response, assuming arguendo that one skilled in the art would be motivated to substitute hydromorphone or oxycodone for morphine in the formulations described in the Paradissis reference, one skilled in the art would not arrive at the presently claimed invention for the reasons set forth above with respect to the anticipation rejection. Therefore, the Examiner is

respectfully requested to remove the obviousness rejection.

CONCLUSION

A check in the amount of $110.00 is enclosed for a one (1) month extension of time. It is believed that no other fees are due at this time. If it is determined that any additional fees are due or that any fees have been overpaid, the Commissioner for Patents is hereby authorized to charge said fees or credit any overpayment to Deposit Account No. 50-0552.

In view of the amendments made and arguments presented, Applicants respectfully submit that the pending claims are in condition for allowance. An early and favorable Action on the merits is earnestly solicited.

Respectfully submitted,

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